

### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Christopher W. Brody on November 23, 2011.

The application has been amended as follows:

In the Claims:

1. (currently amended) A method ~~Method~~ for the species-specific and quantitative detection of central nervous system (CNS) tissue in meat and meat products, comprising the steps:
  - a) preparing of the sample material and RNA extraction
  - b) reverse transcribing of the RNA into cDNA
  - c) analyzing of the cDNA of the ~~glial~~ glial fibrillary acidic protein (GFAP) gene in real-time PCR, wherein the real-time PCR is carried out with a pair of primers selected from the group consisting of ~~comprising~~ a first pair of primers, namely

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SEQ ID NO 1: primer ~~Primer~~ RTGcowM56F2a 5'-ACC TGC GAC CTG  
GAG TCC T-3' and

SEQ ID NO. 2: primer ~~Primer~~ RTGcowM56R2a 5'-CTC GCG CAT CTG  
CCG-3',

a second pair of primers, namely

SEQ ID NO. 4: primer ~~Primer~~ RTGpigM56F2 5'-GAC CTG CGA CGT GGA  
GTC CC-3'

SEQ ID NO. 5: primer ~~Primer~~ RTGpigM56R2 5'-TGG CGC TCC TCC TGC  
TCC -3',

and pairs of primers comprising a forward and a reverse primer having a sequence identity of at least 40% to said first or said second pair of primers;

and wherein the real-time PCR is carried out using a TagMan<sub>mgb</sub> sensor spanning the boundary between exon 5 and exon 6 of the GFAP gene.

2. canceled

3. (currently amended) The method ~~Method~~ according to claim 1 wherein  
~~comprising the fact that the preparation of the sample material occurs by~~  
~~homogenization, preferably by a combination of vertical rotation movements and~~  
~~horizontal up and down movements.~~

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4. (currently amended) The method ~~Method~~ according to claim 1 wherein ~~comprising the fact that~~ the RNA extraction occurs by means of lysis and extraction on phenol basis so that RNA is also extracted from matrices with a ~~particularly~~ high concentration of fatty acids.
5. (currently amended) The method ~~Method~~ according to claim 1 wherein ~~comprising the fact that~~ the real-time PCR is carried out for bovine, ovine and caprine animals with SEQ ID NO. 3 TaqMan<sub>mgb</sub> sensor OptiR 6-FAM-ACT CGT TCG TGC CGC GC-MGB.
6. (currently amended) The method ~~Method~~ according to claim 5 wherein ~~comprising the fact that~~ primer ~~Primer~~ RTGcowM56F2a or primer ~~Primer~~ RTGcowM56R2a is used with the TaqMan<sub>mgb</sub> sensor OptiR.
7. (currently amended) The method ~~Method~~ according to claim 1 wherein the ~~comprising the fact that~~ real-time PCR is carried out for porcine animals with the following primer:  
  
SEQ ID No. 6 TaqMan<sub>mgb</sub> sensor OptiR 6-FAM-ACT CGT TCG TGC CGC GC-MGB.
8. (currently amended) The method ~~Method~~ according to claim 7 wherein ~~comprising the fact that~~ primer ~~Primer~~ RTG RTGpigM56F2 or primer ~~Primer~~ RTG pigM56R2 is used with the TaqMan<sub>mgb</sub> sensor OptiR.

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9. (currently amended) The method ~~Method~~ according to claim 1 wherein the  
~~comprising the fact that it~~ method is carried out in heat-treated meat and meat  
 products.

10. (cancelled)

11. (currently amended) A test ~~[[Test]]~~ kit for the species-specific and quantitative  
 detection of central nervous system (CNS) tissue in meat and meat products,  
 containing, at least, material for the species-specific and quantitative analysis of the  
 GFAP cDNA, wherein ~~comprising the fact that~~ the material for real time-PCR of the  
 extracted GFAP mRNA for the detection of bovine, ovine and caprine animals are  
 Universal PCR Master, MgCl<sub>2</sub>, SEQ ID No. 1: primer ~~Primer~~ RTGcowM56F2a 5'-  
 ACC TGC GAC CTG GAG TCC T-3', SEQ ID No. 2: primer ~~Primer~~ RTGcowM56R2a  
 5'-CTC GCG CAT CTG CCG-3' and SEQ ID No. 3: TaqMan<sub>mgb</sub> sensor OptiR  
 6-FAM-ACT CGT TCG TGC CGC GC-MGB and/or ~~comprising the fact that~~ the  
 material for real time-PCR of the extracted GFAP mRNA for the detection of porcine  
 animals are Universal PCR Master, MgCl<sub>2</sub>, SEQ ID No. 4: primer ~~Primer~~  
 RTGpigM56F2 5'-GAC CTG CGA CGT GGA GTC CC-3', SEQ ID No. 5: primer  
~~Primer~~ RTGpigM56R2 5'-TGG CGC TCC TCC TGC TCC -3' and SEQ ID No. 6:  
 TaqMan<sub>mgb</sub> sensor OptiR 6-FAM-ACT CGT TCG TGC CGC GC-MGB.

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12. (currently amended) The test ~~[[Test]]~~ kit for the species-specific and quantitative detection of CNS tissue in meat and meat products according to claim 11, containing material for RNA extraction as well as suitable reaction buffers and/or material for the reverse transcription of the extracted GFAP mRNA.

13. (currently amended) The test ~~[[Test]]~~ kit for the species-specific and quantitative detection of CNS tissue in meat and meat products according to claim 11, ~~characterised by the fact that~~ wherein the material for the reverse transcription ~~[[of]]~~ and the extraction of mRNA are RNase-free water, reverse transcriptase (RT) buffers, MgCl<sub>2</sub>, 2'-deoxyribonucleoside-5'-triphosphates (dNTP), random hexamers, RNase inhibitor and reverse transcriptase.

14. (currently amended) The test ~~[[Test]]~~ kit for the species-specific and quantitative detection of CNS tissue in meat and meat products according to claim 11, ~~characterised by~~ wherein ~~comprising the fact that~~ a transcription control is contained in the form of a GFAP mRNA for the supervision of a successful transcription process of the isolated GFAP mRNA into cDNA.

15. canceled

16. canceled

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17. (currently amended) The test [[Test]] kit for the species-specific and quantitative detection of CNS tissue in meat and meat products according to claim 11, wherein ~~comprising the fact that~~ the test kit [[it]] contains a positive control in the form of the GFAP cDNA of bovine and/or porcine animals and a negative control in the form of the GFAP cDNA of bovine and/or porcine animals, an internal amplification control as well as reference samples for the quantification of the examined test samples.
18. (currently amended) The test [[Test]] kit for the species-specific and quantitative detection of CNS tissue in meat and meat products according to claim 11, wherein ~~comprising the fact that~~ the reference samples are dilution series, samples with defined CNS content and/or a reference gene.
19. (previously presented) The method according to claim 1, wherein the sequence identity is one of at least 60 %, more than 80 %, and more than 90 %.
20. (new) The method according to claim 3, wherein the homogenization further comprises a combination of vertical rotation movements and horizontal up-and-down movements.

### **REASONS FOR ALLOWANCE**

1. The following is an examiner's statement of reasons for allowance: In view of the amendments, the claimed invention is novel and unobvious over the closest prior art of Seyboldt, Raghavendra, Bouchard, Fahrenkrug and Lowe. No prior art was found that teaches or suggests a method for the species-specific and quantitative detection of central nervous system (CNS) tissue in meat and meat products comprising the steps of preparing the sample material and RNA extraction, reverse transcribing of the RNA into cDNA, analyzing the cDNA of the glial fibrillary acidic protein (GFAP) gene in real-time PCR, wherein the real-time PCR is carried out with a pair of primers selected from a first pair of primers, SEQ ID NOs: 1 and 2, a second pair of SEQ ID NOs: 4 and 5, and a pair of primers comprising a forward and reverse primer having a sequence identity of at least 40% to the first or second pairs of primers, and wherein the real-time PCR is carried out using a TaqMan<sub>mgb</sub> sensor spanning the boundary between exon 5 and exon 6 of the GFAP gene. In addition, no prior art was found that teaches or suggests a kit for the species-specific and quantitative detection of CNS tissue in meat and meat products containing material for the species-specific and quantitative analysis of the GFAP cDNA, wherein the material for real-time PCR of the extracted GFAP mRNA for the detection of bovine, ovine and caprine animals are Universal PCR master mix, MgCl<sub>2</sub> and SEQ ID NOs: 1-3, and/or the material for real-time PCR of the extracted

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GFAP mRNA for the detection of porcine animals are Universal PCR master mix,  $MgCl_2$  and SEQ ID NOS: 4-6.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### **Correspondence**

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David C. Thomas whose telephone number is 571-272-3320 and whose fax number is 571-273-3320. The examiner can normally be reached on 5 days, 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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/David C Thomas/

Examiner, Art Unit 1637

/Kenneth R Horlick/

Primary Examiner, Art Unit 1637